Remarks

Claims 1-22 and 137 are pending. Applicants elected to prosecute the invention of Group I - claims 1-22 and 137, drawn to a method of making dosage forms. Claims 23-136 have been canceled without prejudice to the filing of claims directed to the canceled subject matter in this or a related application.

The Examiner objects to claim 137 as being in improper form for referring to non-elected (and now canceled) claims. Claim 137 has been amended to depend from claims 1 and 14, which are part of the elected group of claims.

The Examiner objects to the specification, page 21, for including a blank space. The space has been replaced with the applicable serial number and publication information. The Examiner objects to the title and requests amending the title to conform to the scope of the pending claims. The title has been amended as requested.

The Examiner rejects claims 1, 6-10 and 137 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,830,502 ("Dong et al."). The Examiner asserts that the reference teaches the claimed process for manufacturing an injection molded dosage form. Applicants respectfully traverse this rejection.

Claim 1 is directed to a method of making a dosage form containing a first medicant. The process requires the steps of injecting through a nozzle a **flowable material containing said first medicant** into a mold cavity and hardening said flowable material into a molded dosage form having a shape substantially the same as the mold cavity. The flowable material injected into the mold cavity must contain at least one medicant.

Dong describes a process for making an osmotic device having an injection molded housing member. The molding compositions contain "thermoplastic polymer, or copolymer, or the compositions comprise a mixture of thermoplastic polymers and optional injection-molding ingredients." Col. 3, lines 8-10. Subsequently, Dong teaches that the compositions can comprise 100% thermoplastic polymer or a blend of polymers, "with all polymers equal to 100%." Col. 3, line 44. Contrary to the Examiner's allegation, there is absolutely no suggestion that the molding compositions could contain a medicament.

The therapeutic agent is taught as being made in conventional manner. One embodiment presses the therapeutic agent into a solid shape that can be pressed into the internal dimensions of the dosage form. A second embodiment presses the therapeutic agent

into a layer for incorporation into the dosage form. See passage in column 4, lines 39-55. The incorporation of a medicament in an outer molded shell would not be consistent with the primary purpose of an osmotic device, which is precise delivery of medicament through an opening using an osmagent and push composition. Hence, Dong fails to disclose at least one material feature of the claimed process - the presence of at least one medicament in the flowable material.

Claim 10 provides that the flowable material comprises gelatin. The specification notes that gelatin is an extremely different material to use as an injection molded material for making dosage forms. Gelatins, once hydrated, have a very abrupt transition temperature between the liquid and solid/gel phases. See publication of instant application, US 2003/0086973 A1, paragraph 173. Gelatins are fundamentally different from thermoplastics in this regard. Consequently, it has not been known for such use in this field.

Dong describes the use of:

> "synthetic resins, for example, linear polycondensation resins, condensation polymerized resins, addition polymerized resins, such as polyamides, resins obtained from diepoxides and primary alkanolamines, resins of glycerine and phthalic anhydrides, polyvinyl resins, polymer resins with end-positions free or esterified carboxyl or carboxamide groups, for example with acrylic acid, acrylic amide, or acrylic acid esters, polycaprolactone, and its copolymers with dilactide, diglycolide, valerolactone and decalactone, a resin composition comprising polycaprolactone and polyalkylene oxide, composition comprising polycaprolactone and a polyalkylene oxide such as polyethylene oxide, cellulose such as hydroxypropylmethylcellulose, hydroxyethylmethylcellulose, hydroxyethylcellulose, and hydroxypropylcellulose, copoly(butylene terephthalate-tetrahydrofuran), copoly(alkylene oxide-methylmethacrylate), and ethylene vinylacetate copolymer.

None of the exemplified resins contemplate a gelatin or gelatin-like material. Hence, Dong fails to disclose an additional feature of the instantly claimed process. For all of the above reasons, Applicants request that the Examiner reconsider and withdraw her anticipation rejection of claims 1, 6-10, and 137 in view of Dong.

The Examiner rejects claims 1-5, 11-13, 21 and 137 under 35 U.S.C. 103 as being unpatentable over Dong. Applicants respectfully traverse this rejection.

Dong does not disclose or suggest having a first medicament in the flowable material used to make the molded dosage form. A medicament is not a proposed or even contemplated optional constituent of the molding compositions taught therein. Dong does not disclose or suggest a process for molding a dosage form wherein gelatin is part of the flowable material. Applicants submit that the Examiner has failed to establish a prima-facie showing of obviousness of the inventions recited in claims 1-5, 11-13, 21 and 137. Applicants request that the Examiner reconsider and withdraw her obviousness rejection in view of Dong.

The Examiner rejects claims 14-20, 22 and 137 under 35 U.S.C. 103 as being unpatentable over Dong in view of U.S. Patent No. 6,177,125 ("Voss et al."). Dong is applied as described above. The Examiner cites Voss as teaching the addition of core or insert in the mold prior to complete molding of the tablet. Applicants respectfully traverse this rejection.

As noted immediately above, Dong does not disclose or suggest having a first medicament in the flowable material used to make the molded dosage form. Dong does not disclose or suggest a process for molding a dosage form wherein gelatin is part of the flowable material. Voss does not disclose an injection molding process[1], nor does Voss describe the use of gelatin material. Voss does not disclose either of these material features of the claimed process, which are lacking in Dong. Assuming the references can be combined, the resulting process does not disclose or suggest the claimed molding process for manufacturing dosage forms. Applicants request that the Examiner reconsider and withdraw her obviousness rejection in view of Dong and Voss.

[1] Applicants were unable to discern a reference to injection molding in column 1, lines 48-57 or claims 1-21, which are directed to pressing/compressing of tablets.

Applicants submit that the present application is now in condition for allowance. Applicants request that the Examiner contact the undersigned representative if minor amendments will further prosecution towards issuance.

Respectfully submitted,

By: David R. Crichton

David R. Crichton
Reg. No. 37,300

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6131
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